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patent.office@novartis.com
maria.stachura@novartis.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ROBERT D. HARGENS, YIMIN JIA,
GREG SLOMINSKI, and SURESH VAYALAKKADA

Appeal 2010-011697
Application 10/566,188
Technology Center 1700

Before TONI R. SCHEINER, DONALD E. ADAMS, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL¹

This is an appeal under 35 U.S.C. § 134 involving claims to a method of producing a taste-masked composition. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the “MAIL DATE” (paper delivery mode) or the “NOTIFICATION DATE” (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

Statement of the Case

Background

“The present invention relates to a taste-masking technology particularly suitable for active administering preparations” (Spec. 1).

The Claims

Claims 1-8 are on appeal. Claim 1 is representative and reads as follows:

1. A process for producing a taste-masked composition comprising an ionic active compound and a functionalized polymer matrix, said process comprising the steps of loading said functionalized polymer matrix with said active compound to produce a loaded matrix, and washing said loaded matrix with a nonpolar solvent.

The issues

A. The Examiner rejected claims 1 and 2 under 35 U.S.C. § 102(b) as anticipated by Hughes² (Ans. 3-4).

B. The Examiner rejected claims 3-8 under 35 U.S.C. § 103(a) as obvious over Hughes and Bess³ (Ans. 5-7).

A. *35 U.S.C. § 102(b) over Hughes*

The Examiner finds that Hughes “teaches a method for the aqueous loading of water soluble and soluble pharmaceutically active substances onto ion exchange resins” (Ans. 3). The Examiner finds that

the claimed washing step of the loaded matrix with a non polar solvent is considered to be met by EP 1175915 wherein it is taught in paragraph [0051] that the water-

² Hughes et al., EP 1,175,915 A1, published Jan. 30, 2002.

³ Bess et al., WO 01/70194 A1, published Sep. 27, 2001.

immiscible solvent can be removed from the final mixture by filtration [0051] and within Example 1 paragraph [0054] wherein after addition of water (it is noted that the water performs the function of the aforementioned water and solvent in paragraph [0020]) and shaking the water is drained from the mixture and within Examples 3-5 in paragraph [0057-0059] wherein the loaded resin is contacted with a non-polar solvent

(Ans. 4).

Appellants contend that to “accomplish its purpose of ‘washing said loaded matrix’ as recited in Claim 1, the claimed nonpolar solvent must not be another solution of the active, which would just re-coat the loaded matrix with active” (App. Br. 9-10). Appellants contend that Hughes “does not teach or suggest a washing step -- it only teaches using an active-containing solution to load active into the matrix” (App. Br. 10). Applicant’s claims and specification are very clear that a washing step is the step subsequent to loading to remove unbound active” (App. Br. 10).

In view of these conflicting positions, we frame the obviousness issue before us as follows: Does the evidence of record support the Examiner’s conclusion that Hughes teaches a step of “washing said loaded matrix with a nonpolar solvent” as required by claim 1?

Findings of Fact

1. The Specification teaches that the “loaded matrix is isolated and washed with a solvent that has a polarity less than an aqueous solvent, preferably with a nonpolar solvent, to remove unbound active compounds” (Spec. 4).

2. The Specification teaches that “the loaded matrix can be washed with a polar solvent, such as the solvent that was used to dissolve the active compound, when more than one washing steps are utilized, provided that the last washing step is conducted with a nonpolar solvent” (Spec. 5).

3. The Specification teaches that the “loaded resin can be briefly washed with a relatively small amount of an alcohol before it is washed with a nonpolar solvent, e.g., hexane” (Spec. 6).

4. Hughes teaches “a method for the aqueous loading of poorly water soluble and soluble pharmaceutically active substances onto ion exchange resins” (Hughes, col. 1 ¶ 0001).

5. Hughes teaches that “using a complex formed between a polymeric material and an active substance can be beneficial. Such benefits can include . . . taste masking of bitter drugs” (Hughes, col. 1 ¶ 0002).

6. Hughes teaches that:

The present invention relates to a method for preparing a resinate comprising the steps of:

- a. blending a poorly water soluble or soluble active substance with an ion exchange resin and a solvent selected from the group consisting of water, a water miscible solvent, a water-immiscible solvent or mixtures thereof to form an active substance/resin/solvent mixture;
- b. maintaining said mixture, at a pressure and temperature that maintains said mixture in the liquid state, for 1 second to 48 hours.

(Hughes, col. 4 ¶ 0020).

7. Hughes teaches that the “addition of a water-immiscible or water miscible solvent as described hereinabove reduces the loading time to between 1 minute and 20 minutes, and eliminates the need to dewater the

mixture. . . .The water immiscible solvent can be removed from the final mixture either by filtration, or by vaporization” (Hughes, col. 7 ¶ 0051).

8. Hughes teaches, in Example 3, addition of water, indomethacin, and TFE to the resin, where after “stirring for 10minutes stop the stirrer and allow the mixture to stand for a few minutes. . . . Carefully remove approximately one half of the TFE as a liquid sample, without including any of the resinate. Remove the TFE from this sample by evaporation” (Hughes, col. 9 ¶ 0057).

Principles of Law

“[A]nticipation of a claim under § 102 can be found only if the prior art reference discloses every element of the claim” *In re King*, 801 F.2d 1324, 1326 (Fed. Cir. 1986) (citing *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458 (Fed. Cir. 1984)).

Analysis

The Examiner argues that the “washing step is not limited with respect to what is being removed or what purity is to be obtained, therefore, the position is taken that the contacting of the loaded resin with solvent as disclosed within the reference is adequate to meet the ‘washing’ step to the extent claimed” (Ans. 7).

We are not persuaded. Claim 1 is reasonably interpreted to require two distinct steps, a step of “loading said functionalized polymer matrix” and a step of “washing said loaded matrix with a nonpolar solvent”. This interpretation is consistent with the Specification, which teaches that after loading, a separate washing step is performed (FF 1-3).

Hughes never teaches a separate washing step with a nonpolar solvent, at best teaching addition of a solution comprising a nonpolar solvent during the loading step, which solution is then removed. This is similar to *ASM America, Inc. v Genus, Inc.*, 401 F.3d 1340, 1344 (Fed. Cir. 2005) where *ASM* argued that a step of evacuating a gas from a chamber also encompassed a step of purging with an inactive gas. However, the Court found that “any doubt on that score is resolved by the language of claim 1, which sets forth evacuation and purging as two distinct steps. . . . The patent clearly requires evacuation through use of a vacuum pump as well as an entirely separate step of feeding an inactive gas into the reaction space.” *Id.* at 1344. The instant claim also sets forth loading and washing as two distinct steps, and there is no support in the Specification which suggests that washing is anything other than an additional step to remove unbound material (FF 1-3).

Conclusion of Law

The evidence of record does not support the Examiner’s conclusion that Hughes teaches a step of “washing said loaded matrix with a nonpolar solvent” as required by claim 1.

B. 35 U.S.C. § 103(a) over Hughes and Bess

The Examiner relies upon Bess to address the limitations of dependent claims. The Examiner does not rely upon Bess to teach a step of “washing said loaded matrix with a nonpolar solvent” as required by claim 1. Therefore, having reversed the anticipation rejection over Hughes for the absence of a teaching of “washing said loaded matrix with a nonpolar

solvent”, we necessarily reverse the obviousness rejections as the Bess reference does not remedy the deficiencies of Hughes.

SUMMARY

In summary, we reverse the rejection of claims 1 and 2 under 35 U.S.C. § 102(b) as anticipated by Hughes.

We reverse the rejection of claims 3-8 under 35 U.S.C. § 103(a) as obvious over Hughes and Bess.

REVERSED

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NOVARTIS CONSUMER HEALTH, INC.
OTC PATENT GROUP
200 KIMBALL DRIVE
PARSIPPANY, NJ 07054-0622